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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/692,063 | 10/23/2003 | David F. Davenport | 03880-P0002B | 7269 |
| 24126 7590 01/25/2008 ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET STAMFORD, CT 06905-5619 | | | | |
| | | | EXAMINER ARNOLD, ERNST V | |
| | | | ART UNIT 1616 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/692,063 | Applicant(s) DAVENPORT ET AL. | |
| | Examiner Ernst V. Arnold | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-38, 40-48, 50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-38, 40-48, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-24, 39 and 49 have been cancelled.

Claims 25-38, 40-48, 50 and 51 are under examination.

Applicant's amendment has necessitated a new ground of rejection. Accordingly, this action is FINAL.

Withdrawn rejections:

Applicant's amendments and arguments filed 9/19/07 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

37 CFR 1.105 Request for Information

Although Applicant did not reply yes or no to the specific request of the presence of lactase in the composition, such information is now irrelevant because Applicant has clearly stated that the invoices do not represent a sale of the product to the public because the product was used only for experimental reasons.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 38 and 38-40 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlothauer et al. (WO 99/65326).

Applicant claims a method for reducing the energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components wherein the composition comprises between about 95% to about 100% whey powder, and between about 1% to about 5% lactase.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Schlothauer et al. teach bioactive whey protein hydrolysate that has a mean particle size of less than about 30 microns (Abstract; and claim 22). Schlothauer et al. teach a process to remove residual lactose by treatment with lactase either before, during or after whey protein hydrolysis (Claim 18). Schlothauer et al. teach a food product containing the whey hydrolysate and a method of reducing blood pressure in a subject which comprises administration to that subject an effective amount of the whey

product (Claims 28, 30 and 31). Schlothauer et al. teach the amount of lactase to use is from 0.3% (enzyme to substrate ratio (page 9, lines 1-2) to 0.4 % w/w (page 12, lines 14-15). Schlothauer et al. do not add fat to their composition.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Schlothauer et al. do not expressly teach a method for reducing the energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components wherein the composition comprises between about 95% to about 100% whey powder, and between about 1% to about 5% lactase.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a food product containing lactase and whey and administer it to a subject as taught by Schlothauer et al. It is the Examiner's position that the administration of a nutritional drink will introduce calories into the subject and therefore reduce the energy deficit. It is an intrinsic aspect of the method.

One of ordinary skill in the art would have been motivated to do this because Schlothauer et al. teach that a nutritional whey protein drink has the health advantages of whey protein. The determination of the amount of lactase to be added to the whey is deemed merely a matter of routine optimization, which one of ordinary skill in the art can perform during ordinary laboratory experimentation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that Schlothauer et al. do not teach administering to a mammal the whey powder and lactase and that lactase is merely used in the processing steps. The Examiner cannot agree with this analysis. Schlothauer et al. clearly state that the lactase can be added after whey hydrolysis (claim 18). Thus, the lactase is present when administered to the subject in the absence of evidence to the contrary.

It is noted for the record that the only examples provided in the specification are directed to treatment of horses (See [00099] for example).

Claim Rejections - 35 USC § 103

Claims 25-38, 40-48, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mahmoud et al. (US 5,104,676) in view of with respect to claims 44 and 48 Hsia (US 6,294,166).

Applicant claims a method for reducing the energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components wherein the composition comprises between about 95% to about 100% whey powder, and between about 1% to about 5% lactase.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Mahmoud et al. teach a weight control product with low lactose milk and a dietary fiber system (Abstract). Mahmoud et al. teach the nutritional information for one serving in column 6, Table III:

| TABLE III | | |
|--|-------------------------|--|
| NUTRITIONAL INFORMATION FOR ONE SERVING OF NEW PRODUCT | | |
| | | Percent of U.S. RDA |
| 30 | Serving Size: | 67.0 g for Vanilla Flavored Product. 71.0 g for Chocolate Flavored Product. |
| | Calories | 240 |
| | Protein | 16 g |
| 35 | Fat | 6 g |
| | Carbohydrate | 30 g |
| | Dietary Fiber | 7 g |
| | Sodium | 500 mg |
| | Potassium | 750 mg |
| | Vitamin A | 1750 IU 35 |
| | Vitamin C | 21 mg 35 |
| 40 | Thiamine (Vitamin B1) | 0.53 mg 35 |
| | Riboflavin (Vitamin B2) | 0.60 mg 35 |
| | Niacin | 7.0 mg 35 |
| | Calcium | 350 mg 35 |
| | Iron | 6.3 mg 35 |
| | Vitamin D | 140 IU 35 |
| 45 | Vitamin E | 10.5 IU 35 |
| | Vitamin B6 | 0.7 mg 35 |
| | Folic Acid | 140 mcg 35 |
| | Vitamin B12 | 2.1 mcg 35 |
| | Phosphorus | 350 mg 35 |
| | Iodine | 52.5 mcg 35 |
| 50 | Magnesium | 140 mg 35 |
| | Zinc | 5.3 mg 35 |
| | Copper | 0.7 mg 35 |
| | Biotin | 105 mcg 35 |
| | Pantothenic acid | 3.5 mg 35 |
| | Chloride | 775 mg 35 |
| 55 | Manganese* | 1.3 mg — |
| | Vitamin K* | 27 mcg — |
| | Selenium* | 24 mcg — |
| | Chromium* | 26 mcg — |
| | Molybdenum* | 50 mcg — |

60 *No U.S. RDA has been established, but these levels do meet the recommendations of other organizations.

Mahmoud et al. disclose that the invention is reconstituted in about 9 oz of water (column 6, lines 17-21). Since 9 oz of water is equivalent to 255.145 g of water, then the amount of fat present in the reconstituted product is less than 3% by weight. Which means that in the 67 g vanilla serving there is about 1.8% of fat, $([6/(67 + 255)] \times 100)$ which reads on about 2% fat. Mahmoud et al. teach using non-fat milk and whey powder and whey protein concentrate (column 8, lines 30-40). Mahmoud et al. teach using oat hull fiber which is insoluble (claim 3). Mahmoud et al. teach treating milk products with lactase to convert the lactose to glucose and galactose (column 13, lines 1-26). Mahmoud et al. teach that participants in a weight loss program may use the invention as a daily replacement for two meals thus reading on a method of reducing energy deficit and maintaining the health of a mammal (column 7, lines 1-5). Thus, Mahmoud et al. teach the composition as providing calories to the participants and would reduce their energy deficit. Protein is made up of amino acids and reads on the 'nutrient component' and 'ingredient' of claims 43, 44 and 47. Mahmoud et al. teach adding sodium chloride to the composition (column 3, line 42).

Hsia teaches a method of improving the health of a mammal comprising orally administering viable lactobacillus acidophilus bacteria (a probiotic), non-living yeast and protein from whey or soy isolates (Abstract and claim 1). The amount of bacteria ranges from about 0.1 to about 10% of the total mass of the composition (Column 4, lines 53-56). The amount of yeast is from about 2.5% to about 20% of the total mass of the composition (Column 5, lines 1-2). The amount of protein is from about 25% to about 98% of the total mass of the compositions (Column 5, lines 6-16).

Fleischner teaches glucosamine in weight loss products (claims 1-7).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and that of Mahmoud et al. is that Mahmoud et al. et al. do not expressly teach a method for reducing the energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components wherein the composition comprises between about 95% to about 100% whey powder, and between about 1% to about 5% lactase.

2. The difference between the instant application and that of Mahmoud et al. is that Mahmoud et al. et al. do not expressly teach a method for reducing the energy deficit in a mammal comprising administering a composition with a prebiotic/probiotic/symbiotic fermentation extract or glucosamine derivatives. This deficiency in Mahmoud et al. is cured by the teachings of Hsai.

3. The difference between the instant application and that of Mahmoud et al. is that Mahmoud et al. et al. do not expressly teach a method for reducing the energy deficit in a mammal comprising administering a composition with glucosamine. This deficiency in Mahmoud et al. is cured by the teachings of Fleischner.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a food product containing lactase and whey powder and administer it to a subject as taught by Mahmoud et al. and reduce their energy deficit and product the instant invention. Mahmoud et al. clearly teach introducing calories into the participant and therefore reducing their energy deficit. It is an intrinsic aspect of the method.

One of ordinary skill in the art would have been motivated to do this because Mahmoud et al. teach that a nutritional whey protein powder and lactase to convert lactose to glucose and galactose. The determination of the amount of lactase to be added to the whey powder is deemed merely a matter of routine optimization, which one of ordinary skill in the art can perform during ordinary laboratory experimentation. Determination of the mesh size of the whey powder is readily performed by one of ordinary skill in the art. The action of lactase enzyme on the whey protein produces monosaccharides as described above which would be in the composition.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Mahmoud et al. for participants to use in a weight loss program with a probiotic as taught by Hsai et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Hsai teaches such probiotics are beneficial to improving the health of a mammal and both inventions are geared towards improving the health of a mammal.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Mahmoud et al. for participants to use in a weight loss program with glucosamine as taught by Fleischner and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because both inventions are directed to the same goal: weight loss.

Summary: It is the position of the Examiner, the instantly claimed methods are intrinsic in the use of the art taught compositions. The components, whey powder, lactase, probiotics etc... are all taught in the art for consumption. One of ordinary skill in the art ingesting such a composition would expect the energy deficit to be reduced.

From recent case law: "the results of ordinary innovation are not the subject of exclusive rights under the patent laws." (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. 550 U. S. ____ (2007) page 24).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

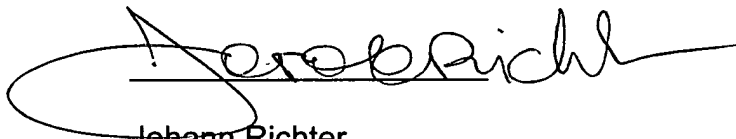
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616

A handwritten signature in black ink, appearing to read "Johann Richter", written over a horizontal line. The signature is fluid and cursive, with a large loop at the beginning.

Johann Richter
Supervisory Patent Examiner
Technology Center 1600